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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/519,164 | 08/30/2005 | Jerome Tauzin | LOM-43 | 5234 |

23599 7590 07/26/2007
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| EXAMINER |
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AUDET, MAURY A

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| ART UNIT | PAPER NUMBER |
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1654

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| MAIL DATE | DELIVERY MODE |
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07/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/519,164 | Applicant(s) TAUZIN ET AL. | |
| | Examiner Maury Audet | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present application has been transferred from former Examiner Young to the present Examiner.

Applicant's amendment and response dated 4/19/07 is acknowledged. New claims 7-14 are pending. It is noted that the new claims have been amended to specifically include three (3) new method claims (assumedly carved out of the single original "use" claim 1):

1. a method of preparation (claim 11);
2. a method of treating hypertension (claim 14); and
3. a method of inhibiting angiotensin I converting enzyme (ACE) (claim 13) [e.g. one pathway along which hypertension is.

It is also acknowledged; though somewhat confusingly by this Examiner, that Applicant has elected a single peptide (SEQ ID NO: 5) as the elected species (not traversed and made FINAL at the last action) - out of two distinct fractions based on peaks: one as SEQ ID NOS: 1-5 (new claim 7) and the other SEQ ID NOS: 1-5 and 8-10 (new claim 11) – even though the claims are drawn to "peptide fractions" which assumedly will never solely constitute a single peptide. [On Applicant's behalf, the Examiner is confused why the methods of making and use are only drawn to SEQ ID NOS: 1-5 (new claim 7); and is curious why/if SEQ ID NOS: 8-10 cannot also be made by the same method and assertedly used to inhibit hypertension and ACE (see e.g. new claims 11 and 13-14 dependencies back to new claim 7)? It is also a curiosity as to whether each distinct peptide (as to SEQ ID NOS: 1-5) is able to carry out the purported methods of use (which appears true based on the election of the single SEQ ID NO: 5); or if only a peptide fraction comprising ALL of SEQ ID NOS: 1-5 carries out the methods of use, as a reasonable

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interpretation of the claims would infer]. Notwithstanding all of the above, this Examiner is presently willing continue the examination on the merits as to the new method claims and the election of SEQ ID NO: 5 (species); as opposed to sending out a restriction based either on 8 distinct peptides, or even two apparently distinct "peptide fraction" compositions, comprising distinct peptides therein, one of which may be used to carry out the methods, the other apparently not.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of new claims 7-10 and 12 under 35 U.S.C. 102(b) as being anticipated by Matoba et al., Zucht et al., Brignon et al., and Garault et al., is maintained for the reasons of record, as established by the former Examiner. Applicant's arguments have been considered but are not deemed persuasive. The claims are to a product (elected SEQ ID NO: 5), which is known. Applicant's arguments that the references do not teach "peptide fractions" is irrelevant, based on Applicant's election of SEQ ID NO: 5. Unless, Applicant intended lexicography of "peptide fraction" of SEQ ID NO: 5 is to limit SEQ ID NO: 5 to less than the total peptide, such must be established on the record by Applicant and positively claimed. Until such clarification (assuming support may be found), the election of SEQ ID NO: 5 and rejection based on it's well known status, stands.

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Claim Rejections - 35 USC § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of new claims 7-8, 11, 13, and 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for the reasons of record.

Applicant has provided arguments other than to say the “rejection is moot in view of the amendments”. This is wholly unpersuasive as concerns the former Examiner’s 4-page detailed explanation as to why the elected SEQ ID NO: 5 is enabled as a food product, but not enabled for e.g. treating/preventing hypertension.

Thus, the rejection of the claims as lacking enablement for the following reasons is maintained:

1. SEQ ID NO: 5 has not been established as capable of treating hypertension (e.g. claims 7, 8, 11), nor one of it’s underlying pathways – as capable of inhibiting ACE (e.g. claims 7 and 13); and
2. SEQ ID NO: 5 has not been established as having a credible “pharmaceutical” use) (e.g. claim 8).

Claim Objections

Claim 7 is objected to because of the following informalities: the first recitation of HPLC and ACE should be spelled out fully (like was done in claim 13), followed by the shortened form in parenth’s. Appropriate correction is required.

Conclusion

Applicant's amendment (in part) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

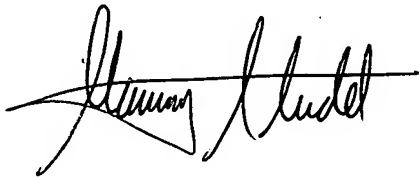
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/21/2007



MAURY AUDET
PATENT EXAMINER



CHRISTOPHER R. TATE
PRIMARY EXAMINER